MAR 1 9 2002

510(K) Summary

Pursuant to 510 (i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name: Sulzer Dental Inc.
Address: 1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number: 760-929-4300
Registration Number : 2023141
Contact Person: Sean Hariri
Date Summary Prepared: December 17, 2001
Classification Name: Endosseous Dental Implant
Common/Usual Name: Abutment for Dental Implant System
Device Trade Name: Sulzer Dental Ceramic System-Spline

The Primary device used for comparison in this summary is the Gold Coping Abutment (K943180) and the FRIALIT®-2 CeraBase Abutment (K980630)

1. Intended Use:

The Sulzer Dental Ceramic System - Spline is intended for use specifically for anterior and premolar, single-unit cement-retained restorations. This product should not be used in the molars and should not be splinted together for multiple unit cases, partials or bridgework.

2. Description:

The Ceramic System-Spline uses a titanium Spline core (abutment) and a ceramic coping. The core is attached to the implant with a titanium retaining screw. The coping is cemented to the core for a final restoration. The core will be offered in three implant interface diameters, 3.25mm, 4.0mm, and 5.0mm. The Ceramic System coping is available in six shapes: small incisor, 17° small incisor, large incisor, 17° large incisor, canine, and premolar.

3. Technological Characteristics:

The Ceramic System-Spline is an additional abutment design for the Spline Dental implant system. The system consists of two parts, the titanium alloy abutment and the ceramic coping. The abutment will be fixed to the implant with a titanium alloy screw. The net ceramic coping will be bonded with porcelain by the laboratory to fabricate the finalized coping. The finished restoration is then cemented to the abutment.

4. Comparison Analysis:

The abutment of the Ceramic System-Spline is similar to the Sulzer Dental Gold Coping Abutment and the FRIALIT®-2 CeraBase Abutment. The ceramic coping of the Ceramic

System is similar to commercial crowns used to fabricate a restoration. See **Table 1** below for a comparison of the Ceramic System and the predicate systems.

Feature	Sulzer Dental Ceramic System-Spline	Predicate: Sulzer Dental Gold Coping Abutment	Predicate: FRIALIT-2® CeraBase Abutment
Intended Use	Anterior Single Unit Restoration Cases	Anterior/Posterior Single-Unit and Multi-Unit Restoration Cases	Anterior Single Unit Restoration Cases
Abutment Body Geometry	Tapered Retentive Wall	Straight Retentive Wall	Straight RetentiveWall
Abutment/Implant Interface Diameter	3.25mm, 4.0mm, and 5.0mm	3.25mm, 4.0mm, and 5.0mm	3.8mm, 4.5mm, 5.5mm, & 6.5mm
Abutment Cuff Flare Dimater	4.5mm	4.5mm and 6.5mm	Variable
Abutment Body Material	Titanium Alloy (Ti-6Al-4V)	Gold Alloy	Pure Titanium grade II
Implant/Abutment Interface	Spline anti-rotational interface	Spline anti-rotational interface	Hex anti-rotational interface
Ceramic Coping Material	Zirconia Toughened Alumina	N/A	Aluminum Oxide
Manufacturing Site	Carlsbad, CA	Carlsbad, CA	Meinnheim, Germany
Packaging	PETG tray and Tyvek® lid	PETG tray and Tyvek® lid	Blister pack combined w/ cardboard outer wrap.
Sterile	No	No	No

Table: 1 Summary of Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2002

Mr. Sean Hariri
Regulatory Affairs Associate
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K014214
Trade/Device Name: Sulzer Dental Ceramic System-Spline
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Hariri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014214

510(K) Number (if known): K014214

Device Name: Sulzer Dental Ceramic System-Spline

Indications for Use: The Sulzer Dental Ceramic System - Spline is intended for use specifically for anterior and premolar, single-unit cement-retained restorations. This product should not be used in the molars and should not be splinted together for multiple unit cases, partials or bridgework.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014214